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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,238	03/02/2002	Rong Xiang	TSRI 830.0	6584

7590 09/25/2003

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/090,238	XIANG ET AL.	
	Examin r	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2003* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-35 are pending.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, 10, 19, drawn to a DNA vaccine encoding a ECA antigen and a CD40 ligand and method of using the same, which is made by a single plasmid, classified in class 514, subclass 44.

II. Claims 1, 3-5, 8-9, 10-13, 14, and 16-18, 20, drawn to a DNA vaccine encoding a ECA antigen and a CD40 ligand, and method of using the same, which is made by two plasmids that are both operably incorporated in an attenuated bacterial delivery vector, classified in class 424, subclass 258.1.

III. Claims 1, 6-7, 9, 10, 15-18, drawn to a DNA vaccine made by two plasmids that are both operably incorporated in an attenuated viral delivery vector, classified in class 435, subclass 320.1.

IV. Claims 21-24, 27-30, drawn to a method for immunizing a mammal against cancer cells by using a DNA vaccine a ECA antigen and a CD40 ligand plus humanKS1/4 and IL-2, wherein the DNA vaccine is carried by a bacterial delivery vector, classified in class 435, subclass 2.

V. Claims 21, 25-30, drawn to a method for immunizing a mammal against cancer cells by using a DNA vaccine a ECA antigen and a CD40 ligand plus humanKS1/4 and IL-2, wherein the DNA vaccine is carried by a viral delivery vector, classified in class 424, subclass 93.1.

VI. Claims 21, and 31, drawn to a method for immunizing a mammal against cancer cells by using a DNA vaccine a ECA antigen and a CD40 ligand plus humanKS1/4 and IL-2, wherein the DNA vaccine is carried by a single plasmid, classified in class 435, subclass 2.

VII. Claims 21, and 32, drawn to a method for immunizing a mammal against cancer cells by using a DNA vaccine a ECA antigen and a CD40 ligand plus humanKS1/4 and IL-2, wherein the DNA vaccine is carried by two separate plasmid DNAs, classified in class 434, subclass 41.

VIII. Claims 33-34, drawn to a kit comprising a DNA vaccine encoding a CD40 ligand and ECA antigen, classified in class 435, subclass 975.

IX. Claims 33 and 35, drawn to a kit comprising a DNA vaccine encoding a CD40 ligand and ECA antigen plus huKS1/4-IL2, classified in class 424, subclass 193.1

2. This application contains claims directed to the following patentably distinct species of the claimed invention: Species of bacterial vectors: 1). Selmonella typhinium and 2). Listeria moncytogenes. Species of viral vectors: a). Herpes virus, b. Adenovirus , c). vaccinia virus and d). Avipox virus.

3. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, for the species of bacterial vector, claims 5, 13, and 24 are generic. For the viral vector, claims 7, 15 and 26 are generic.

4. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

5. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions are distinct, each from the other because of the following reasons:

7. Inventions of groups I-III and VIII-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the

instant case the different inventions of different groups are directed structurally and functionally different products, e.g. the DNA vaccine in group I is carried by a plasmid, whereas the DNA vaccine is a viral vector.

8. Inventions of groups IV-VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, different groups are directed different methods that use different products and produce different biological results, e.g. the method of group IV is to use a DNA vaccine encoding a CEA and CD40 ligand, whereas the method of Groups VIII is to use the DNA vaccine plus hKS1/4-IL2.

9. Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product, such as a polypeptide rather then a DNA vaccine.

10. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

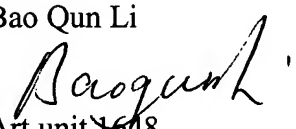
12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

15. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li



Art unit 1648

September 15, 2003